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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,103	08/08/2001	David M. Goldenberg	018733-1055	9967

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FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,103

Applicant(s)

GOLDENBERG ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 6,8-17 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 18-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. The Response to the Restriction Requirement filed 7/10/2002 (paper no. 9) is acknowledged. Upon further review and reconsideration, the inventions of group I (claims 1-5, and 7) and VI (claims 18-21) will be rejoined and examined on the merits.
2. Claims 1-24 of the instant application are pending. Claims 6, 8-17, and 22-24 are withdrawn from consideration as being drawn to a non-elected invention. Applicant is reminded to cancel all non-elected claims.
3. Therefore, claims 1-5, 7 and 18-21 are examined on the merits.

Information Disclosure Statement

4. The Information Disclosure Statement filed 2/7/2002 (paper no. 4) is acknowledged and considered. A signed copy of the IDS is attached hereto.

Claim Objections

5. Claim 7 is objected to because of the following informalities: the recitation of the term "antobody", is "antibody" intended? Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

6. Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The terms "anti-NCA-90" and "anti-NCA-95" are abbreviations of antigen names, which must be accompanied by the full name of the antigen.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 3, 5, and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is apparent that the recited antibodies are required to practice the claimed invention, because they are specifically required in the claims. As required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the hybridoma representing the specifically named antibodies. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the antibodies of claims 3, 5, and 20, and they do not appear to be readily available material. Deposit of the cell lines would satisfy the enablement requirements of 35 U.S.C. 112.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

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If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

- (a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;
- (b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;
- (d) a viability statement in accordance with the provisions of 37 CFR 1.807; and
- (e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 112, 1st paragraph

7. Claims 1-5, 7, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating CML comprising the administration of hMN-3 and further comprising the administration of an anti-CD33 antibody does not reasonably provide enablement for a method of treating CML with any naked granulocyte antibody, any NCA-90 antibody, and any NCA-95 antibody. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification of the instant application teaches the administration of a specific granulocyte antibody (hMN3) that recognizes the NCA-90 antigen for the treatment of CML. The specification also teaches the co-administration of hMN3 with an anti-CD33 antibody for the treatment of CML. However, nowhere in the specification does it teach the use of any and all types of anti-granulocyte antibodies, nor does it teach the administration of any NCA-95 antibodies for the treatment of CML. Furthermore, the specification has not taught how to administer two granulocyte antibodies for the treatment of CML. As stated in the specification, depending on the stage of CML, this disease may be relatively difficult to treat (see page 1). Although the specification has described in a prophetic manner the methods of treating CML with hMN3, and the combination of hMN3 with CD33 antibodies, there is no actual data showing the side effects, the end points needed, the specific dosages, intervals and response rates observed in using the instantly claimed antibodies. Furthermore, the

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specification has not taught what if any effects other antibodies, such as those classified as NCA-95 antibodies, would have on the treatment of CML, because there is a lack of working examples associated with those antibodies. As such, the specification has not taught one of skill in the art the necessary steps to practice the instant invention because there is a lack of defined outcomes, dosages, and usage of any and all anti-granulocyte antibodies. Therefore, the specification of the instant invention has only enabled a method of treating CML with hMN3 or hMN3 in combination with CD33 antibodies. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

8. Because we are under compact prosecution, the following rejection under 35 USC 102(b) can be made.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 5, and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Seybold K (Nuclear Medicine Communications, (1988) 9/10:745-752). Claims are drawn to a method comprising the administration of a therapeutic composition

comprising a pharmaceutical carrier and a granulocyte antibody. Seybold K teaches the administration of an monoclonal antibody that reacts with NCA-95 to a subject. The intended usage of the instant claims as recited in the preamble does not carry any patentable weight.

Claim Rejections - 35 USC § 102

11. Because we are under compact prosecution, the following rejection under 35 USC 102(b) can be made.

12. Claims 1 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Caron PC *et al* (IDS A2). Claims 1 and 7 are drawn to a method of administering an anti-granulocyte antibody wherein the antibody can be among other things a humanized antibody. Caron PC *et al* teach an anti-granulocyte antibody, HuM195, which is reactive against CD33. Furthermore, Caron *et al* also teach the use of this antibody in the treatment of CML. The intended usage of the instant invention as recited in the preamble of the claims does not carry any patentable weight as it applies to prior art.

Claim Rejections - 35 USC § 102

13. Because we are under compact prosecution, the following rejection under 35 USC 102(a) can be made.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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15. Claims 1, 7, 18, and 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Thomas *et al* (IDS A1). Claims 1,7,18, and 21 are drawn to a method comprising the administration of an anti-granulocyte antibody, wherein the antibody can be amongst other things the antibody is monoclonal, and the method can also further comprise at least two anti-granulocyte antibodies, wherein one of the additional antibodies is a CD15 antibody. Thomas *et al* teach a method of treating CML comprising the administration a multitude of antibodies directed against granulocytes. The antibodies dclained by Thomas *et al* are monoclonal and can also be anti-CD15 antibodies.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaeh whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Christopher Yaen

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February 24, 2003


ALI R. SALIMI
PRIMARY EXAMINER